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EXPEDITED PROCEDURE
EXAMINING GROUP 2643
PATENT APPLICATION
Attorney's Do. No. 1420-2

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In The United States Patent and Trademark Office

In re Patent application of: David William House

Serial No. 09/478,136 Group No. 2643

Filed: January 5, 2000 Examiner: D. Harvey

Title: **COCHLEAR IMPLANTS WITH A STIMULUS IN THE HUMAN ULTRASONIC RANGE AND METHOD FOR STIMULATING A COCHLEA**

Date: April 22, 2002

BOX AF
Commissioner of Patents and Trademarks
Washington, D.C. 20231

TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Enclosed for filing in the above-referenced application are the following:

☒ Appellant's Brief (in triplicate)
☒ Filing Fee - $160
☒ PTO Form 2038 authorizing credit card payment for the above-listed fees is enclosed.
☒ Any deficiency or overpayment should be charged or credited to deposit account number 13-1703. A duplicate copy of this sheet is enclosed.


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Date of Deposit: April 22, 2002

Mary Dennis

PATENT APPLICATION
Attorney's Do. No. 1420-2

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In re Patent application of: David William House

Serial No.	09/478,136	Group No.	2643
Filed:	January 5, 2000	Examiner:	D. Harvey

Title: **COCHLEAR IMPLANTS WITH A STIMULUS IN THE HUMAN ULTRASONIC RANGE AND METHOD FOR STIMULATING A COCHLEA**

ATTENTION: Board of Patent Appeals and Interferences
Commissioner of Patents and Trademarks
Washington, D.C. 20231

APPELLANT'S BRIEF

UNDER 37 CFR §1.192

Appeal is taken from the Examiner's Office Action mailed February 22, 2002, finally rejecting claims 1-12 in the instant application.

This Appeal Brief is in furtherance of the Notice of Appeal mailed in this case on March 21, 2002.

The fees required under §1.17(c) and any required petition for extension of time for filing this Brief and fees therefor are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This Brief is transmitted in triplicate.

This Brief contains these items under the following headings, and in the order set forth below.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

37 CFR §1.192(c) (1)

The real party in interest is as named in the caption of this Brief.

II. RELATED APPEALS AND INTERFERENCES

37 CFR §1.192(c) (2)

The Board's decision in the present Appeal will not directly affect, or be directly affected, or have any bearing on any other appeals or interferences known to the appellant, or to the appellant's legal representative.

There is no assignee.

III. STATUS OF CLAIMS

37 CFR §1.192(c) (3)

Status of Claims:

1. Claims presented: 1-18
2. Claims withdrawn from consideration but not cancelled: NONE
3. Claims canceled: 13-18
4. Claims pending: 1-12, all of which are subject to the instant Appeal. These appealed claims 1-12 are eligible for appeal, having been finally rejected.

IV. STATUS OF AMENDMENTS

37 CFR §1.192(c) (4)

Subsequent to the Final Office Action mailed on September 26, 2001, rejecting claims 1-12:

* Appellant filed an Amendment After Final Rejection, attempting to amend independent claims 1, 7.

* An Advisory Action was received by Appellant, mailed February 22, 2002, reporting that:

a) the After Final Amendment was not being entered, but would be entered upon the timely submission of the Notice of Appeal and Appeal Brief; and

b) when the After Final Amendment would be entered, it would overcome the section 112 rejection of the Final Office Action.

* Appellant filed the Notice of Appeal on March 21, 2002, with no other correspondence.

* Appellant is hereby filing the instant Brief, in following up with the Notice of Appeal. Appellant therefore expects that the After Final Amendment is being entered prior to the Board considering the instant Brief. Appellant therefore assumes that the section 112 rejection to the claims of the Final Office Action has been overcome, thereby leaving only the section 103 rejections at issue in this Appeal.

V. SUMMARY OF THE INVENTION
37 CFR §1.192(c) (5)

The present invention relates to inducing hearing in patients with hearing loss. More particularly, the present invention provides cochlear implant systems, and a method for stimulating a cochlea.

Referring to Fig. 4 of the instant application, the system includes an internal unit 132 and an external unit 150. Internal unit 132 includes at least one electrode 134 for coupling with the patient's cochlea 30. Internal unit 132 also includes an internal (implanted) coil assembly 140 to inductively drive the electrode 132. External unit 150 includes a microphone 154 for producing electrical signals in response to external sounds (depicted by sound waves 24).

Referring to Fig. 5, in one embodiment of the invention, external unit 154 also includes an oscillator 157 for generating an electrical analog carrier signal, and a modulator 160 for modulating the carrier signal with the sound signals to generate a modulated signal. An external coil assembly (156, Fig. 4) magnetically couples the modulated signal to the internal coil assembly 140.

The analog carrier signal has a frequency in the ultrasonic human range, i.e. greater than 20,000 Hz, such as 32,000 Hz or 80,000 Hz. This higher frequency results in clearer rendering of sounds, and a higher frequency range of rendered sounds.

Referring to Fig. 7, a method according to the invention is for stimulating a human cochlea in response to a sound. The method includes generating an electrical sound signal in response to the sound (box 210), and generating an electrical analog carrier signal having a frequency greater than 20 kHz (box 220). The carrier signal is modulated with the sound signal to generate a modulated signal (box 230), and the modulated signal is applied to an electrode that is coupled with the cochlea such that carrier signal is applied to the cochlea (box 240).

VI. ISSUES ON APPEAL
37 CFR §1.192(c) (6)

ISSUE 1: Whether claims 1-12 are unpatentable under 35 U.S.C 103(a) over the Applicant's Admitted Prior Art ("APA") in view of Loeb (US 5,571,148).

ISSUE 2: Whether claims 1-12 are unpatentable under 35 U.S.C 103(a) over the Applicant's Admitted Prior Art ("APA") in view of Puharich (US 3,586,791).

[NOT AN ISSUE: Whether claims 1 and 7 are unpatentable under 35 U.S.C. §112, second paragraph. See Examiner's Final Action, ¶ 2. The Applicant's offered amendment will be entered, and that rejection will be overcome.]

VII. GROUPING OF CLAIMS
37 CFR §1.192(c) (7)

The appealed claims may be classified in two groups:

A) For group of method claims 1-6, the independent claim is claim 1.

B) For group of system claims 7-12, the independent claim is claim 7.

VIII. ARGUMENT
37 CFR §1.192(c) (8)

ARGUMENT COMMON TO BOTH ISSUES:

The invention is novel and nonobvious, in that it teaches *to stimulate the cochlea also with a supersonic signal* to generate a percept. That is not found in the prior art. Novel elements are unobvious under 103.

The prior art in the field teaches away from stimulating the cochlea with a supersonic signal. All prior art references of record that teach to stimulate the cochlea, do so with a signal having a frequency in the sonic range.

These prior art references include the Admitted Prior Art (APA) of the instant application. But while the APA indeed teaches to stimulate the cochlea, it does not do that with a *supersonic* signal.

The two rejections are based on hypothetical combinations of the Admitted Prior Art (APA) with each of two other references (Loeb, Puharich).

The rejections are respectfully traversed, and are the subject of this appeal.

ARGUMENT FOR ISSUE 1: Claims 1-12 are patentable under 35 U.S.C 103(a) over the Applicant's Admitted Prior Art ("APA") in view of Loeb (US 5,571,148).

Applicant repeats the common to both issues argument made above.

Loeb does not teach to stimulate the cochlea by applying a supersonic signal to it. Indeed, what reaches the cochlea in Loeb is stimulation pulses, which have a frequency in the sonic range (not the supersonic range as claimed). As such, Loeb does not teach the invention as claimed.

While Loeb does use a supersonic carrier, it only does that to transfer a sonic-range signal wirelessly to the implanted unit, through the skin of the patient. The sonic-range signal is transferred in a modulated form, but then it is demodulated (i.e. extracted) from the high frequency carrier. Only sonic-range signals are then applied to the implanted electrodes.

As per Loeb's Fig. 3, an electrode array 36 is implanted in a cochlea 52.

Accordingly, cochlea 52 only receives the signal that excites the electrodes of array 36.

Now reference is made to Loeb's Fig. 4A, which is reproduced below:

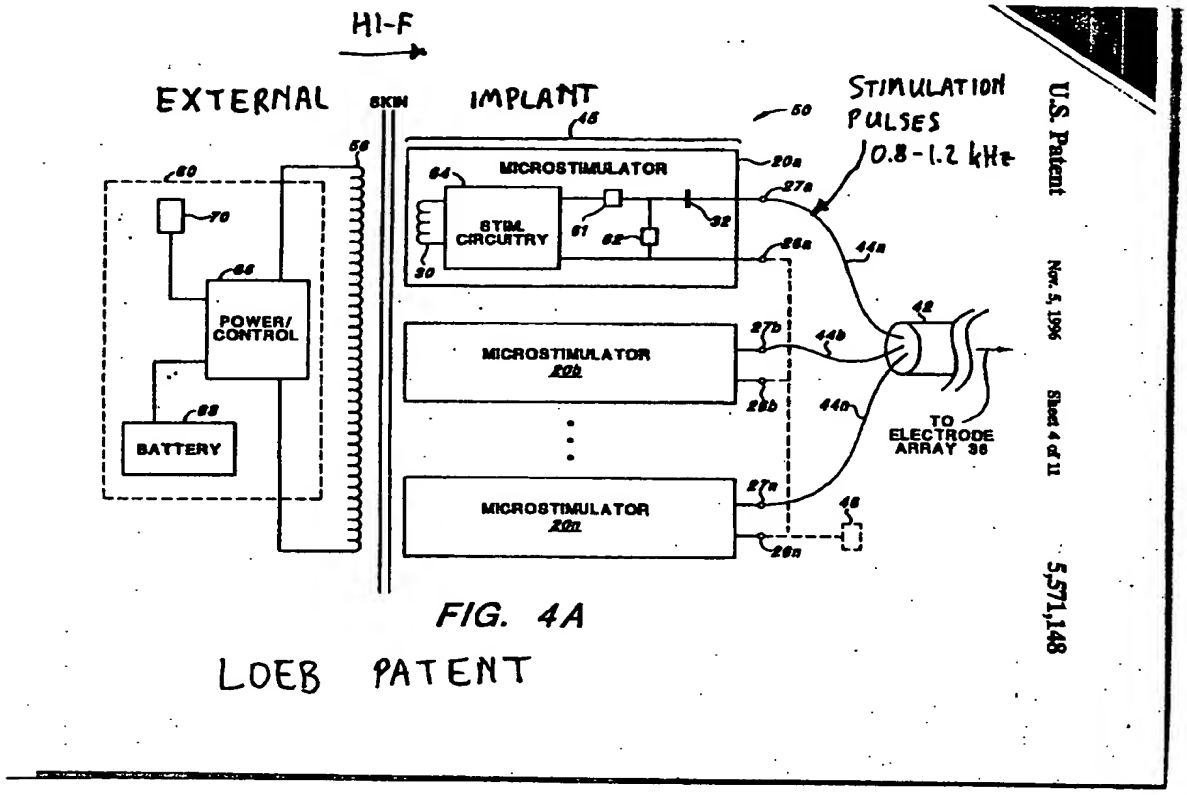

FIG. 4A

LOEB PATENT

Loeb characterizes Fig. 4A as "a functional block diagram of a multichannel stimulator made in accordance with the present (meaning Loeb's) invention, illustrating both the implantable and the non-implantable portions thereof;" (Loeb, col. 6, l. 37-41).

Referring to Loeb's Fig. 4A, skin separates an external processor 60 (col. 11, l. 9) from an implanted array 45 of microstimulators 20a, 20b, 20c, ..., 20n. These microstimulators have wire conductors 44a, 44b, 44c, ..., 44n, which are connected to electrode array 36. (Col. 10, l. 48-51.)

The sonic-range signal is received at input transducer 70 (col. 11, l. 44) of external processor 60. The sonic range signal is modulated at power control circuit 66, which includes an oscillator to generate the carrier signal, and a suitable modulator to modulate the carrier signal, and ... inductive coil 56. (Col. 11, l. 35-39). The carrier signal is at a

high frequency, namely between 100 – 5000 kHz. (Col. 11, l. 11-12.)

The modulated high frequency signal travels wirelessly through the skin, and is received by Loeb's implanted microstimulators 20a, 20b, 20c, ..., 20n. Of those, microstimulator 20a is shown in more detail in Fig. 4A. It includes a coil 30 and a stimulation circuitry 64. (Col. 10, l. 55-56.)

Details of stimulation circuitry 64 are shown in Loeb's Fig.s 7A and 7B. In both cases, a demodulator is shown.

Returning to Loeb's Fig. 4A, the wirelessly high frequency traveling signal is received by coil 30, and then transferred to stimulation circuitry 64. Then stimulation circuitry 64 may be triggered or not, depending on whether the signal received at coil 30 contains a suitable address. (Col. 11, l. 16-27).

Each microstimulator, when triggered, produces a stimulation pulse through its own set of electrodes. (Col 11, l. 27-29). In all cases, the stimulation pulse emerges from the demodulators of Fig 7A, 7B.

Loeb's stimulation pulses are the only signal applied to Loeb's electrode array 36. Therefore, the frequency of the stimulation pulses is the only frequency that reaches and is applied to the cochlea.

These stimulation pulses that are applied to the cochlea have a triggering rate of 800-1200 pulses per second (col. 14, l. 43). This corresponds to a frequency of 0.8 kHz to 1.2 kHz. That frequency is in the sonic range, and not the supersonic range of the claimed invention.

Even Loeb characterizes that rate of 800-1200 pulses per second as a "relatively fast rate" (col. 14, l. 43). Accordingly, Loeb does not suggest operating at a higher triggering rate than the sonic range for exciting the cochlea.

The rejection is founded in suggesting that the high frequency (100 – 5000 kHz) carrier and/or modulated signal is used to excite the cochlea. That is respectfully traversed. Those high frequency signals are not applied to the electrodes. Instead, Loeb goes to lengths (microstimulator 20a, demodulator in microstimulator 20a) to produce stimulation pulses that have a sonic range frequency (0.8 kHz to 1.2 kHz). It is these stimulation pulses of sonic range that are applied to the electrodes for stimulating the cochlea.

In maintaining the rejection, the Examiner writes that "the carrier signal of Loeb

reaches the electrode *via* microstimulators". That is also respectfully traversed. The high frequency carrier is used by Loeb only to transfer power and information about the signal-of-interest (control) though the skin. But all that is output from the microstimulators is the stimulation pulses. None of Loeb's higher frequency carrier goes *past* the microstimulator on to the cochlea.

As such, it is respectfully requested that this rejection be withdrawn.

ARGUMENT FOR ISSUE 2: Claims 1-12 are patentable under 35 U.S.C 103(a) over the Applicant's Admitted Prior Art ("APA") in view of Puharich (US 3,586,791).

Applicant repeats the common to both issues argument made above.

APA and Puharich work differently in inducing a sound percept to the patient. They solve different problems in different ways. That is why they are not properly combinable for an obviousness determination.

Indeed, as mentioned above, the APA works by stimulating a cochlea. The APA assumes that the cochlea works.

Puharich, on the other hand, does not even teach to stimulate the cochlea. Puharich bypasses the cochlea, and even assumes that the cochlea need not.

Instead of stimulating the cochlea, Puharich works by stimulating the exposed facial nerve system. On this point, Puharich writes explicitly:

> "In case of total deafness, even when there is strong evidence that the nerves of the cochlea have been totally destroyed by an infectious process, hearing may be achieved by the practice of the invention." (Puharich, column 7, lines 9-12).

A person skilled in the art would not extend Puharich's facial nerve system to include the cochlea (as would be necessary for combining with the APA in forming a fair rejection). That is because the cochlea is substantially encased in bone, while the Puharich signals are applied to exposed facial nerves. These facial nerves are identified to include the exposed head and neck regions of the subject. (Col. 3, lines 30-34). Puharich's facial nerves may be excited by dermal electrodes. Dermal means of or relating to the skin. In

fact, these dermal electrodes of Puharich's are to be "placed properly against the skin of the subject" (col. 3, line 39). Those are a far cry from the *implant* in the cochlea of the present invention.

[In maintaining the rejection, the second time around the Examiner omitted the word "facial" from the characterization of Puharich's "facial nerves". This way Puharich's term "facial nerves" is quoted as only "... nerves" in the Final Office Action. The Board ought not to be confused by this.]

Therefore, a person having ordinary skill in the art would not combine the references. To work through a working cochlea, the person would look to the APA, discarding Puharich. To work inspite of a damaged cochlea, the person would look to Puharich, discarding the APA.

The rejection exploits the fact that Puharich stimulates at high frequency. But it is common knowledge that the choice of frequency is made from considering what part of the body the person skilled in the art is interested in stimulating. For example, Puharich chose a high frequency *because* Puharich is interested in stimulating the facial nerve system that bypasses even a damaged cochlea. But to determine the frequency for stimulating a healthy cochlea itself, one would not look to Puharich.

As such, it is respectfully requested that this rejection be withdrawn.

APPENDIX

37 CFR §1.192(c) (9)

The text of appealed claims 1-12 (after the amendment will be entered) will be as follows:

1. (Twice Amended) A method for stimulating a human cochlea in response to a sound, comprising:

generating an electrical sound signal in response to the sound;

generating an electrical analog carrier signal having a frequency greater than 20 kHz;

modulating the carrier signal with the sound signal to generate a modulated signal; and

applying the modulated signal to an electrode that is coupled with the cochlea such that carrier signal is applied to the cochlea.

2. The method of claim 1, wherein modulating is by amplitude modulation.

3. The method of claim 1, wherein modulating is by frequency modulation.

4. The method of claim 1, wherein the electrical analog carrier signal has a frequency of at least 32 kHz.

5. The method of claim 4, wherein modulating is by amplitude modulation.

6. The method of claim 4, wherein modulating is by frequency modulation.

7. (Twice Amended) A cochlear implant system for a patient's cochlea comprising:

at least one electrode for coupling with the patient's cochlea;

an internal coil for implanting in the patient to drive the electrode;

a microphone for outputting electrical sound signals in response to external sounds;

an oscillator for generating an electrical analog carrier signal having a frequency greater than 20 kHz;

a modulator for modulating the carrier signal with the sound signals to generate a modulated signal; and

an external coil for magnetically coupling the modulated signal to the internal coil such that the carrier and the modulated signal are applied to the cochlea.

8. The system of claim 7, wherein the modulator is an amplitude modulator.

9. The system of claim 7, wherein the modulator is a frequency modulator.

10. The system of claim 7, wherein the electrical analog carrier signal has a frequency of at least 32 kHz.

11. The system of claim 10, wherein the modulator is an amplitude modulator.

12. The system of claim 10, wherein the modulator is a frequency modulator.

X. CONCLUSION

The Appellant requests favorable consideration by the Board. If any questions remain, please call the undersigned.

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Very truly yours,

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